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Practical cross-border insights into pharmaceutical advertising

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products is regulated by Laws No. 6,360 of 1976, No. 8,078 of 1990 ("CDC"), No. 9,294 of 1996 and Resolution RDC No. 96 of 2008 issued by the National Health Surveillance Agency ("ANVISA"). It is further regulated under codes of practice, such as the Brazilian Advertising Self-Regulation ("CONAR") Code and Interfarma's Code of Conduct.

1.2 How is "advertising" defined?

Advertising is broadly defined by ANVISA's Resolution RDC No. 96/2008 as "a set of information and persuasion techniques and activities aiming to disseminate knowledge, make a determined product or brand better known and/or prestigious, to exert influence on the public through actions intended to promote and/or induce the prescription, dispensing, acquisition and use of a drug".

Advertising is also defined under the CONAR Code as "all activities designed to stimulate consumption of products and services and promote institutions, concepts or ideas". The CDC defines advertising as "any information, sufficiently accurate, conveyed by any form of communication and related to products or services offered to consumers".

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

According to article 36 of the CDC, companies must keep all information related to factual, technical and scientific data that supports the advertising of a product as evidence. Moreover, article 27(1) of the CONAR Code establishes that advertisers must be able to supply all documentary evidence of descriptions, assertions and comparisons relating to facts that support the advertising of a product.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no such requirements under the Brazilian legislation.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

As a rule, advertising of pharmaceutical products does not have to be approved in advance by any regulatory authority.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

ANVISA may order the advertiser to suspend the advertising and issue a rectifying message in case it violates sanitary legislation under Federal Law No. 6,437/1977. Such order will be made in the context of an administrative procedure in which the company will have the right to present a defence. There are rights of appeal within ANVISA's administrative procedure. Moreover, in case of illegality, it is possible to challenge ANVISA's final decision before a court of law.

In addition to ANVISA, consumer defence authorities (the municipal/state ones, called "PROCONs", or the National Consumer Secretariat ("SENACON")) may also notify the advertiser, ordering the suspension of the advertisement and publication of a counter-advertisement in case they deem that a certain part of the advertisement violates consumer laws. The company will have the right to present a defence in an administrative proceeding, and the final decision may also be challenged before the judiciary.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Under sanitary rules, the penalties for failing to comply with the rules governing the advertising of medicines include: warning; fine (from BRL 2,000 up to BRL 1.5 million); prohibition of advertising; suspension of the sale of the advertised product; imposition of a rectifying message; product apprehension, destruction or interdiction; and suspension of advertising. ANVISA has responsibility for enforcement, and whenever violations are detected, the rules are strictly enforced.

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From a consumer defence point of view, the penalties for violation of advertising rules include: fine; prohibition or suspension of the advertising; and imposition of a counter-advertisement. In case the misleading or abusive advertisement constitutes crimes against consumers, then the penalty is imprisonment from three months up to one year and payment of a fine. Enforcement of the rules is carried out by the PROCONs, SENACON or the courts. The rules are strictly enforced by those authorities, especially in relation to products related to the health of consumers.

Anyone (including competitors) can present a complaint to the authorities about advertising infringements. A competitor can also file a lawsuit with regard to such infringements.

There are several cases in which ANVISA or PROCONs have fined companies because of misleading or abusive advertising, and in terms of the Superior Courts, there have been many cases in which the legality of those fines was recognised. Finally, the Public Prosecutor can file a collective lawsuit, asking for damages due in relation to abusive advertising, and each consumer might, individually, file lawsuits asking for any damages they might have suffered due to abusive and/or misleading advertising.

The violators of the rules established in the CONAR Code will be subject to the following penalties: (i) warning; (ii) recommendation to modify or correct the advertisement; (iii) recommendation to the media to suspend the broadcasting of the advertisement; and (iv) disclosure to the media of CONAR's position as regards the advertiser, the agency and the medium for non-compliance with the measures determined by the entity. CONAR's Superior Committee has responsibility for the enforcement of the decisions of the Ethical Council in a regular process. In 2021, there were several important examples of actions being taken against pharmaceutical companies under the CONAR Code.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

There is no link between ANVISA's enforcement of advertising and any self-regulatory body or industry association. Any breach may be investigated by the competent authority and any self-regulatory body or industry association independently. ANVISA cannot base its decision on the findings identified by the self-regulatory body or the industry association, but the findings may complement the authority's investigation.

The self-regulatory process and the enforcement function of competent consumer entities are also independent. Any consumer entity may independently and additionally investigate any breach of the law, even if the matter is already being investigated by a self-regulatory body, and both entities can apply sanctions on the company for the same breach.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Competitors may bring a claim based on unfair competition only if: (i) the competitors are in the market at the same time; (ii) the competitors operate in the same or related sectors; and (iii) the competitors operate in the same geographic space.

The injured party may bring civil and criminal actions at the same time. Based on the Brazilian Industrial Property Law (Law No. 9,279/96), unfair competition is considered a crime punishable with three months to one year of imprisonment or fines. Regardless of the criminal action, the injured party may also file civil claims under the Brazilian Civil Procedure Code. In civil cases, the compensation will be determined by the benefits that the injured party would have received if the violation had not occurred plus damages.

It is also possible to file a claim against employers, partners or managers of the same company. In this case, the criminal penalties may be increased by one-third to a half.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

According to ANVISA's Resolution RDC No. 96/2008, the provision of promotional materials relating to medical products registered before ANVISA must be in strict accordance with the product's registration. Consequently, information on off-label indications or on non-registered products is prohibited.

Although ANVISA's Resolution RDC No. 96/2008 is applicable to the industry's relationship with the general public, the distribution of information about unregistered products is expressly prohibited by the legislation and restricted not only for consumers/the general public, but also for healthcare professionals ("HCPs").

Additionally, Interfarma's Code of Conduct establishes that clinical studies related to products or indications unregistered with ANVISA may be handed out to HCPs only upon their request, or when provided in medical and scientific events. Also, Interfarma's Code of Conduct determines that information on off-label indications or on non-registered products must only be shared and discussed within the medical area and/or Medical Scientific Liaison ("MSL") of the company, without the participation and/or presence of the commercial area. Thus, any such product may be discussed at scientific events, regardless of whether or not the event is sponsored by the company responsible for the product.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

Information on unauthorised medicines and/or off-label information may be published as scientific information in media specialised in health.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

Yes, this is possible; however, only scientific information may be

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published, and only in media specialised in health. This information cannot be directed to the general public.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

Information on unauthorised medicines or off-label information may be sent to HCPs only upon their request, or when provided in medical and scientific events, (i) when the audience is composed of HCPs only, and (ii) upon express disclosure of the non-authorised status of the product or use with the competent bodies.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

This decision has not been reflected in the legislation or practical guidance in Brazil.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

No. Disclosing information about unauthorised medicines or off-label indications is prohibited, except to HCPs upon their request. Thus, such information may not be sent to institutions to enable then to plan ahead their budget for products to be authorised in the future.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Companies may involve HCPs in market research exercises concerning possible launch materials, but must not interfere with their autonomy and must respect their technical-scientific independence.

However, Interfarma's Code of Conduct states that companies must not involve HCPs in their promotional activities, which would be considered a violation of the Code of Medical Ethics.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

According to ANVISA's Resolution RDC No. 96/2008, the information that must be included in advertising to HCPs is as follows: (i) brand name; (ii) name of the active ingredient as written in the Common Brazilian Denomination; (iii) registration number; (iv) indications; (v) counter-indications; (vi) warnings related to adverse reactions and interactions with other substances; (vii) dosage; (viii) prescription and dispensing classification; and (ix) date of printing.

In case the promotional piece on a prescription-only medicine highlights the benefits of the medicine, the piece must also highlight at least one counter-indication and one frequent medicine interaction.

For vaccines, advertisements must provide the necessary number of doses for complete immunisation.

Products containing substances under special control are subject to further regulation.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Information that appears in an advertisement must be in strict conformity with the registration information of the product.

Studies not included in the SmPC may be used as references in an advertisement to HCPs. However, they must be published in scientific publications, preferably with high evidence levels, and must be available for delivery to HCPs and/or the authorities upon request.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The inclusion of medical endorsements in medicine advertising is forbidden. Resolution 1,974/201 of the Federal Council of Medicine prohibits medical doctors from "participat[ing] in advertising of companies or products associated with medicine".

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

No. Any such comparison must be based on studies that have been published.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

ANVISA's Resolution RDC No. 96/2008 and industry association codes govern comparative advertisements. According to ANVISA's rules, price comparisons with other medicines must be exclusively between medicines that are interchangeable or that have the same active ingredient. Additionally, Interfarma's Code of Conduct states that comparative promotional materials must comply with the principles established by the association and respect some limitations, especially the fact that the use of third-party brands without the consent of their respective owners is not allowed. This prohibition does not cover the performance of comparative advertising between active ingredients and other characteristics linked to the composition of medicines, although it is possible to indirectly identify the companies and adherents, provided that it is properly grounded in comparative studies.

Unauthorised products cannot be mentioned in advertising.

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3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

ANVISA's Resolution RDC No. 96/2008 and industry association codes. According to ANVISA's rules, scientific papers may only be distributed to HCPs and any sponsorships must be informed.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

Yes, as there are no regulations directly related to this matter.

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

Pharmaceutical products, as instructed by the Brazilian legal and regulatory framework, can only be promoted for the indications expressly included in the product's registration package. Additionally, when promoting any product, the expression "combined use indication" must be included in the product's SmPC.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

It is possible to provide HCPs with samples of medicinal products. ANVISA's Resolution RDC No. 60/2009 provides for the requirements for the distribution of free samples of medicinal products: (i) it must be carried out by companies to the prescribing professionals; (ii) by means of documented acceptance; and (iii) in outpatient clinics, hospitals, medical and dental offices.

Companies cannot offer free samples of biological products that require special conditions for their transportation and products prepared in compounding pharmacies.

The free sample package must contain 50% of the original content, except for: products for chronic diseases and contraceptives, which must have the same content of the registered original; and antibiotics, which must have a complete treatment for the patient.

The registration holder of the product must keep on file, for a minimum of two years, all documents related to the production, distribution and pharmacovigilance data of the free samples and must send information on the production and distribution of free samples to ANVISA annually.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

No, this is not allowed. According to article 5 of ANVISA's Resolution RDC No. 96/2008, which governs the promotion of medicines, "companies cannot grant, offer, promise or distribute gifts, benefits and advantages to prescribers or dispensers, those who sell the product directly to the consumer, as well as to the general public".

Interfarma's Code of Conduct reinforces such prohibition. However, certain items may be exempt from this prohibition, such as pens and notepads (made available at in-person seminars/events with the company logo and not the logo of the product) and items essential for the safe use of the product prescribed by the HCP.

It is worth highlighting that stricter guidance may apply to HCPs acting in the public practice, in view of the risks associated with potential violations of the Brazilian Anti-Corruption Law.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

Donations to healthcare organisations ("HCOs") must comply with a legitimate interest and always be aimed at meeting the real needs of the assisted community or society. There is no monetary limit, but the donation amount must be reasonable in relation to the aim of the donation.

It is highly recommended that companies formalise each donation by means of an agreement (letter agreement or similar written instrument) outlining the clear purpose, type, amount of the donation and other conditions that donors and recipients must comply with.

Cash donations are usually allowed. However, donations of products or services are preferred over cash to avoid further risks. In addition, companies are encouraged to address guidance for the recipients on the use of these resources in line with the purpose of the donation and should consider including additional monitoring or auditing measures on that aspect and anti-corruption clauses.

Donations to public HCOs require extra caution. In this context, companies must pay close attention to specific requirements from legal provisions issued at federal, state and local levels, as additional conditions may apply.

At the federal level, Decree No. 10,314/2020 governs donations of products and services to public federal entities (including HCOs). Some of the measures required by this Decree are the registration of the products or services on a website of the Government and restrictions on the publicity or advertising these donors can carry out in relation to this type of donation.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

Although ANVISA's Resolution RDC No. 96/2008 prevents

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companies from providing, offering, promising or distributing small gifts, benefits or advantages to prescribing or dispensing HCPs, Interfarma's Code of Conduct allows companies to provide medical or educational goods and services to HCPs, as long as it is not related to the compulsory prescription, promotion, recommendation, indication or endorsement of the company's products by the HCP. Companies cannot interfere with the HCP's autonomy and must respect their technical-scientific independence.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

There are no restrictions on this matter; however, the arrangement cannot be executed in a manner that fosters indiscriminate use of medicines or suggests or stimulates diagnosis.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

No. This is not possible as it could be considered a violation of article 5 of ANVISA's Resolution RDC No. 96/2008.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

No. This type of scheme is forbidden by the National Code of Self-Regulation in Advertising and Interfarma's Code of Conduct.

4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?

There is no specific regulation on this topic; however, risk-sharing agreements with companies from the pharmaceutical industry are valid legal arrangements, especially when related to high-cost medicines.

4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

The Brazilian health system includes various players, such as public and private hospitals, health insurance companies, the federal and local health authorities, etc., therefore various rules can apply. There are various possibilities of cooperation in joint projects between pharmaceutical companies and HCPs and HCOs, from both the private and public sector.

Interactions with public authorities require extra caution and company representatives must be well trained for that purpose. Also, in some partnerships and joint ventures, companies must comply with bidding rules (when applicable) and other specific legal requirements.

4.10 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Yes, pharmaceutical companies may sponsor continued medical education as long as certain requirements are met. Most importantly, companies cannot bound the sponsorship to the compulsory prescription, promotion, recommendation, indication or endorsement of the company's products by the HCP.

Also, according to article 42, §1º of ANVISA's Resolution RDC No. 96/2008, any sponsorship of a company to any events, symposia, congresses, meetings, conferences and similar, public or private, whether partial or total, must be clearly stated at the time of registration of participants and during the proceedings.

Recordkeeping is crucial. The sponsor relationship and the payment/reimbursement of expenses related to admission, hospitality and meals must be duly documented.

4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

There are no specific legal provisions related to anti-bribery/anti-corruption on the interactions between the industry and HCPs and/or HCOs. The general legal provisions on anti-bribery include: (i) Federal Decree No. 2,848/1940 ("Criminal Code"); (ii) Federal Law No. 12,846/2013 ("Anti-Corruption Law"); (iii) Federal Decree No. 8,420/2015 ("Administrative Proceeding for Violations of the Anti-Corruption Law"); (iv) Federal Law No. 8,429/1992 ("Administrative Misconduct"); and (v) Federal Law No. 14,133/2021 ("Public Bidding Law").

Most of the anti-bribery guidance applicable and best practices adopted by the healthcare industry are issued by industry associations, such as Interfarma. As members of these associations, companies must acknowledge and comply with such practices, which address potential anti-corruption risks (such as the granting of gifts, hospitality, sponsorships, interactions with public authorities and HCPs working for the public sector) and establish penalties in case of violations.

With respect to the enforcement of anti-bribery provisions by Brazilian authorities, the Anti-Corruption Law establishes that the highest Government body or agency is the competent authority to investigate any violations. Therefore, health authorities, such as ANVISA, have jurisdiction to investigate anti-corruption cases. However, violations of advertising rules will be restricted to investigations by ANVISA, consumer authorities and CONAR.

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5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Except for article 5 of ANVISA's Resolution RDC No. 96/2008, there is no specific provision regarding offering of hospitality.

However, according to Interfarma's Code of Conduct, supporting expenses in relation to transportation, meals and accommodation are allowed, but some limitations apply: the expenses must be limited to the event and the period that the event will occur; the expenses must be related solely to the invited HCP; the values must be modest; and the location suitable for the exchange of information. Thus, there is no limitation as regards to the location of the event, but it must be appropriate/adequate to the event's scientific purpose.

The support cannot be conditioned to the prescription, sale or promotion of a medicine or a company by the HCP.

Finally, with regard to events, the invited HCPs may not receive any kind of compensation, direct or indirect, for the time invested in monitoring the event, except when such compensation corresponds to services legitimately provided as a result of a contractual obligation previously agreed.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Yes, it is possible to pay an HCP in connection with attending a scientific meeting. Expenses with hospitality must be limited to events of a scientific or educational nature.

Companies can pay for travel, accommodation, meals, enrolment fees or expenses strictly related to the event itself. Payment or reimbursement of leisure and entertainment expenses is not allowed.

It is highly recommended that companies formalise these grants through a sponsorship agreement, including, for example, a description of the event and its purpose, the amount/expenses covered, reimbursement rules and clauses addressing potential conflicts of interest.

Companies are not allowed to pay an HCP for time if he/she is only attending the event as a participant. However, HCPs can be hired to provide training sessions or lectures.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

In cases where ANVISA finds that a company's conduct represents a violation of the sanitary legislation (such as undue promotion of products), the consequences for the company would probably be a fine (that may vary from BRL 2,000 up to BRL 1.5 million).

If a sponsorship or hospitality arrangement is considered a breach of the Brazilian Anti-Corruption Law (i.e., it is considered a promise or an offer of undue advantage to a public official or their third-party intermediary), the fines applicable range from 0.1% to 20% of the company's gross revenues in the year prior to the commencement of the investigation.

In case the grant or sponsorship is considered an ethics violation in connection with Interfarma's Code of Conduct, companies can be subject to the following penalties: written warning or retraction; suspension or exclusion from the association; and a fine ranging from BRL 5,000 to BRL 1.65 million.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

Yes, this is possible; however, the company cannot bind the hiring of the HCP to the compulsory prescription, promotion, recommendation, indication or endorsement of the company's products by him/her.

Also, the company cannot interfere with the HCP's autonomy and must respect their technical-scientific independence.

The remuneration must be adequate and aligned with the fair market value and with his/her professional experience, as well as with the complexity and importance of his/her professional services. In addition, expenses with regard to transport, accommodation and food may be paid, provided they are reasonable, limited to the extent necessary for the provision of the contracted service.

There must be a document proving the adjustment between the parties with a description of the nature of the services to be provided and the criteria for the remuneration of these services.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

The same rules as provided in the answer to question 5.4 will apply.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

The same rules as provided in the answer to question 5.4 will apply.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes, advertising of non-prescription medicines to the general public is allowed if the medicine is registered with ANVISA.

There are several restrictions on the advertising of medicines, the most important of which are:

(i) the company must not promote off-label use or an unregistered device;

(ii) the company cannot foster indiscriminate use of medicines, suggest or stimulate diagnosis, suggest that a medicinal product is tasty, yummy or delicious, or include any image of a person taking the medicine;

(iii) the medicine's ANVISA registration number must be indicated in advertising material;

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(iv) all clinical and therapeutic claims in advertising material related to the medicine must be based on substantiated scientific data having clinical and statistical significance;
(v) information inserted in advertising material must be coherent with the information provided to ANVISA and with duly published and approved technical literature and scientific papers, as well as in accordance with regulation and legal requirements;
(vi) all advertising material must be truthful and non-misleading, coherent and consistent with the visual, artistic and copy plan;
(vii) adverting of over-the-counter ("OTC") medicines must contain warning messages; and
(viii) companies are not allowed to provide, offer, promise or distribute small gifts, benefits or advantages to prescribing or dispensing HCPs or to the general public. There are exceptions, such as institutional small gifts (which do not advertise medicines), scientific materials, such as technical books, and educational materials for professional update.

In addition, all advertising of these products must comply with the CDC, i.e. must be objective, indicate all risks for the health and safety of consumers, and cannot be abusive or misleading.

The CONAR Code regulates the advertisement of OTC pharmaceuticals products. According to its most important rules, an advertisement must not:

(i) Be made so as to induce the use of products by children without parental guidance.
(ii) Induce the consumer to error concerning the content, package size, appearance, use, speed of relief, or therapeutic action of the product and its classification.
(iii) Contain affirmations or dramatisations that may induce the reader or spectator to fear or distress that he/she has or may have, without treatment, any serious disease.
(iv) Contain offensive comparisons with competitors, unless it is easily perceived by the consumer or based on scientifically verifiable evidence.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No. The advertising of prescription-only medicines to the general public is forbidden.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Yes, disease awareness campaigns are allowed. However, it must be highlighted that it is prohibited to mention any medicine on such campaign or foster the use of medicines or suggest or stimulate diagnosis.

Also, the campaign cannot indicate a specific doctor to the patients. The campaigns must only encourage the population to consult their doctors.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

There is no legal provision/restriction on this topic. Our understanding is that press releases concerning prescription-only medicines, as long as they are considered advertising by the authorities, must only be issued to scientific journals.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

There is no legal provision/restriction on this topic. However, corporate brochures/Annual Reports must not take the form of advertising and must not serve as an inducement to the consumption of any medicine.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

There is no express legal or regulatory provision governing the relationship between pharmaceutical companies and patient organisations. However, certain practices may be considered irregular by law enforcement authorities, mainly if the relationship results in or is perceived as an inducement of prescription-only medicines or a disguised promotional activity, or if the patient organisation is used by the company as a vehicle to influence doctors or induce prescription.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

ANVISA's Resolution RDC No. 96/2008 determines that companies are not allowed to provide, offer, promise or distribute small gifts, benefits or advantages to the general public, which includes patients.

6.8 What are the rules governing company funding of patient support programmes?

Although companies commonly implement patient support programmes ("PSP") in Brazil, there is no rule governing such practice. The lack of specific rules (and, therefore, of express prohibition) could initially lead to the interpretation that a PSP can be freely implemented.

However, as the distribution or offer of any other type of object or service to patients and/or HCPs is prohibited, in theory, PSPs may be at risk before ANVISA.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

According to Resolution CNS No. 466/2013, the researcher of a clinical trial has the duty to publish the results of their research. The researcher is also responsible for submitting the periodical and final reports of their research to the authorities. However, the company sponsoring the trial has no such obligation.

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7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

Although there is no specific legal provision addressing requirements in relation to transfers of value to HCPs, HCOs and patient organisations, there are some rules governing disclosure of some sponsorships, grants and donations. Companies must pay close attention to specific requirements from legal provisions issued at federal, state and local levels.

Article 42, §1º of ANVISA's RDC Resolution No. 96/2008 sets forth that any sponsorship of a company to any events, symposia, congresses, meetings, conferences and similar, public or private, whether partial or total, must be clearly stated at the time of registration of participants and in the annals, if applicable.

As a general rule for donations of products and services to federal entities (including public HCOs), Decree No. 10,314/2020 requires the registration of the products or services the company wishes to donate on a special website of the Government.

Furthermore, with regard to local regulation, the State of Minas Gerais requires pharmaceutical, orthosis, prosthetics, equipment and implant companies to report on a specific website any type of grants to HCPs registered with the professional council within the State of Minas Gerais made directly or by third parties, such as gifts, tickets, event registration, lodging, financing of research stages, consulting, lectures, continued and permanent education, social and recreational events, commission, bank transfers or payments in cash, financing of clinical guidelines or articles of opinion and financing of societies and professional associations for purposes of conflict-of-interest analysis (State Law No. 22,440/2016, regulated by Decree No. 47,334/17).

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Please refer to question 7.2.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Companies can include a clause in the sponsorship, donation or service agreements addressing the consent or authorisation for public disclosure of such transfers of value. This could prevent any future liabilities or assist the company in case it wishes to enforce the disclosure in court.

8 Digital Advertising and Social Media

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

This type of advertising is regulated by the same Resolution that regulates other forms of advertising (ANVISA's Resolution RDC No. 96/2008). There are only a few specific provisions in this Resolution focused on Internet advertising; for example, in relation to how warnings must appear.

All of the CDC rules apply to Internet advertising, including the need for transparency and the prohibition of misleading or abusive advertising.

The CONAR Code has provisions regarding advertising OTC pharmaceutical products on the Internet and CONAR published, in 2021, the Digital Influencer Advertising Guidelines.

Also, the Brazilian Internet Act (Law No. 12,965/2014) sets the principles, guarantees, rights, and duties for users and providers of the Internet in Brazil. Although this Law does not encompass Internet advertising and/or marketing, it regulates the responsibility for damages arising from content generated by third parties on the Internet.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

There are no specific levels of website security provided for by law. In any case, companies must carefully evaluate what information they will make generally available on their websites and what information is accessible only upon the submission of prior credentials or registration to avoid being penalised by the authorities.

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

In both cases, the rules that will apply are those provided for in ANVISA's Resolution RDC No. 96/2008, especially the one determining that medicines under prescription cannot be advertised and that any indirect advertising may be considered illegal. A pharmaceutical company may be deemed responsible for the irregular content included on a website if this pharmaceutical company supported in any way the promotion of the content.

From a consumer's perspective, the company will be held responsible for the content of the website in either case. In Brazil, all of the suppliers in a chain are equally responsible for any damages or breaches of the law towards consumers (so-called "joint and several liability").

The company can also be held liable under article 19 of the Brazilian Internet Act, which states that providers of Internet applications can be civilly liable for damages resulting from content generated by third parties if, after a specific court order, they do not remove the content identified as infringing.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Pharmaceutical companies may include the company's history, its portfolio and product leaflets. In relation to OTC medicines,

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the company may include promotional information, observing the rules mentioned in the answer to question 6.1.

Please note that, pursuant to the CDC, all information accessed by the public must be clear and accurate, with specifics on quantity, quality, composition, price, and on any potential risks the product may present regarding the health and safety of consumers.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

CONAR published, in 2021, the Digital Influencer Advertising Guidelines, which contain instructions for content generated by digital influencers on social media, which could include OTC pharmaceutical products.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

There are no restrictions on this activity.

8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

There is no legal provision concerning interactions with HCPs conducted virtually. Generally, this matter is provided for in the Ethics Code applicable for the HCP, which is not applicable for the industry, but only for the HCP, and in Codes of Conduct issued by different industry associations.

As a good practice and considering Ethics Codes applied by the industry, companies are allowed to interact with physicians and other HCPs for promotional and non-promotional purposes, provided that the following principles are respected: (i) autonomy; (ii) transparency; and (iii) integrity.

Relations between the industry and HCPs must respect their technical-scientific independence, observing that the physician is also free to prescribe the treatment he/she considers more appropriate for the patient.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

No significant developments occurred in the last year.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

No significant developments are expected in the next year (since pharmaceutical advertising is not part of ANVISA's agenda for the years 2022–2023).

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

In the context of the COVID-19 pandemic, we have seen agencies becoming active in preventing advertisement of off-label use of medication for treatment of COVID-19.

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